



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 526, 529, and 558

[Docket No. FDA-2013-N-0002]

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 43 approved new animal drug applications (NADAs) and 3 approved abbreviated new animal drug applications (ANADAs) from Boehringer Ingelheim Vetmedica, Inc. to Strategic Veterinary Pharmaceuticals, Inc.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002 has informed FDA that it has transferred ownership of, and all rights and interest in, the following 43 approved NADAs and 3 approved ANADAs to Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503:

Table 1.--Applications Transferred	
Application No.	Trade Name
11-531	DIZAN (dithiazanine iodide) Tablets
11-674	DIZAN (dithiazanine iodide) Powder
12-469	DIZAN Suspension With Piperazine
31-512	ATGARD (dichlofos) Swine Wormer Type A Medicated Article
33-803	TASK (dichlofos) Dog Anthelmintic
35-918	EQUIGARD (dichlofos)
38-200	MEDAMYCIN (oxytetracycline hydrochloride) Soluble Antibiotic
39-483	BIO-TAL (thiamylal sodium) Injectable Solution
40-848	ATGARD C (dichlofos) Swine Wormer Type A Medicated Article
43-606	ATGARD V (dichlofos) Swine Wormer Type A Medicated Article
45-143	OXYJECT (oxytetracycline hydrochloride) Injectable Solution
47-278	OXY-TET 50 (oxytetracycline hydrochloride) Injectable Solution
47-712	BIZOLIN-100 (phenylbutazone) Tablets
48-010	ANAPLEX (dichlorophene and toluene) Capsules
48-237	EQUIGEL (dichlofos) Oral Gel
48-271	TASK (dichlofos) Tablets
49-032	ATGARD C (dichlofos) 9.6% Type A Medicated Article
55-097	DRY-MAST (penicillin G procaine/dihydrostreptomycin sulfate) Intramammary Infusion
65-178	FERMYCIN (chlortetracycline hydrochloride or chlortetracycline bisulfate) Soluble Powder
65-461	ANACETIN (chloramphenicol) Tablets
65-481	Chlortetracycline Pneumonia/Calf Scour Boluses
65-486	Chlortetracycline Bisulfate Soluble Powder
65-491	MEDICHOL (chloramphenicol) Tablets

65-496	Tetracycline Soluble Powder
92-837	NEMACIDE (diethylcarbamazine citrate) Oral Syrup
93-516	BIZOLIN (phenylbutazone) Injection 20%
97-452	OXYJECT 100 (oxytetracycline hydrochloride) Injectable Solution
98-569	MEDACIDE-SDM (sulfadimethoxine) Injection 10%
99-618	BIZOLIN (phenylbutazone) 1-G Tablets
108-963	MEDAMYCIN (oxytetracycline hydrochloride) Injectable Solution
109-305	Oxytocin Injection
117-689	NEUROSYN (primidone) Tablets
125-797	Nitrofurazone Dressing
126-236	Nitrofurazone Soluble Powder
126-676	D & T (dichlorophene and toluene) Worm Capsules
127-627	NEMACIDE-C (diethylcarbamazine citrate) Tablets
128-069	NEMACIDE (diethylcarbamazine citrate) Chewable Tablets
132-028	ANESTATAL (thiamylal sodium) Powder for Injection
135-771	Methylprednisolone Tablets
136-212	Methylprednisolone Acetate Injectable Suspension
137-310	Gentamicin Sulfate Injectable Solution
138-869	Triamcinolone Acetonide Injectable Suspension
140-442	Xylazine HCl Injection
200-023	Gentamicin Sulfate Intrauterine Solution
200-029	Ketamine Hydrochloride Injection
200-165	SDM (sulfadimethoxine) 12.5% Oral Solution

Accordingly, the Agency is amending the regulations in 21 CFR parts 510, 520, 522, 524, 526, 529, and 558 to reflect the transfer of ownership.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, 526, and 529

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 524, 526, 529, and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In the table in paragraph (c)(1) of § 510.600, alphabetically add an entry for “Strategic Veterinary Pharmaceuticals, Inc.”; and in the table in paragraph (c)(2), numerically add an entry for “054628” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503	054628
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
054628	Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503
* * * * *	

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.390a [Amended]

4. In paragraph (b)(1)(i) of § 520.390a, remove “000010” and in its place add “054628”.

§ 520.441 [Amended]

5. In paragraph (b)(3) of § 520.441, remove “000010” and in its place add “054628”.

§ 520.443 [Amended]

6. In paragraph (b) of § 520.443, remove “000010” and in its place add “054628”.

§ 520.580 [Amended]

7. In paragraph (b)(2), remove “000010 and 000061” and in its place add “Nos. 000061 and 054628”.

§ 520.600 [Amended]

8. In paragraph (c) of § 520.600, remove “000010” and in its place add “054628”.

§ 520.622a [Amended]

9. In paragraph (a)(6) of § 520.622a, remove “000010” and in its place add “054628”.

§ 520.622b [Amended]

10. In paragraph (c)(2) of § 520.622b, remove “000010” and in its place add “054628”.

§ 520.622c [Amended]

11. In paragraph (b)(6) of § 520.622c, remove “000010” and in its place add “054628”.

§ 520.763a [Amended]

12. In § 520.763a, remove and reserve paragraph (a); in paragraph (c), remove “000010” and in its place add “054628”; and remove paragraph (e).

§ 520.763b [Amended]

13. In § 520.763b, remove and reserve paragraph (a); and in paragraph (c), remove “000010” and in its place add “054628”.

§ 520.763c [Amended]

14. In paragraph (b) of § 520.763c, remove “000010” and in its place add “054628”; and remove and reserve paragraph (c).

§ 520.1408 [Amended]

15. In paragraph (b) of § 520.1408, remove “000010” and in its place add “054628”; and remove and reserve paragraph (c).

§ 520.1660d [Amended]

16. In § 520.1660d:

a. In paragraph (b)(3), remove “000010” and in its place add “054628”.

b. In paragraph (d)(1)(ii)(A)(3), remove “000010” and in its place add “054628”.

c. In paragraph (d)(1)(ii)(B)(3), remove “000010” and in its place add “054628”.

d. In paragraph (d)(1)(ii)(C)(3), remove “000010” and in its place add “054628”.

§ 520.1720a [Amended]

17. In paragraph (b)(2) of § 520.1720a, remove “000010 and 000859” and in its place add “000859 and 054628”.

§ 520.1900 [Amended]

18. In paragraph (b) of § 520.1900, remove “000010” and in its place add “054628”; and in paragraphs (c)(1), (c)(2), and (c)(3), remove the footnote.

§ 520.2220a [Amended]

19. In paragraph (a)(1) of § 520.2220a, remove “000010, 000069, 000859, 054925, and 057561” and in its place add “000069, 000859, 054628, 054925, and 057561”.

§ 520.2345d [Amended]

20. In paragraph (b)(2) of § 520.2345d, remove “000010” and in its place add “054628”.

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

21. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1044 [Amended]

22. In paragraph (b)(3) of § 522.1044, remove “000010” and in its place add “054628”.

§ 522.1222a [Amended]

23. In paragraph (b) of § 522.1222a, remove “000010, 000859, 061690, 026637, and 063286” and in its place add “000859, 026637, 054628, 061690, and 063286”.

§ 522.1410 [Amended]

24. In paragraph (b) of § 522.1410, remove “000010” and in its place add “054628”.

§ 522.1662a [Amended]

25. In paragraphs (a)(2), (b)(2), (g)(2), and (h)(2) of § 522.1662a, remove “000010” and in its place add “054628”.

26. In § 522.1680, revise the section heading to read as set forth below; and in paragraph (b), remove “000010, 000856, 000859, and 061623” and in its place add “000856, 000859, 054628, and 061623”.

§ 522.1680 Oxytocin.

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27. In § 522.1720, revise the section heading to read as set forth below; and in paragraph (b)(2), remove “000010” and in its place add “054628”.

§ 522.1720 Phenylbutazone.

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28. In § 522.2220, revise the section heading as set forth below; and in paragraph (c)(2), remove “000010” and in its place add “054628”.

§ 522.2220 Sulfadimethoxine.

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29. In § 522.2424, revise the section heading as set forth below; and in paragraph (b), remove “000010 and 000856” and in its place add “000856 and 054628”; and remove paragraph (c)(4).

§ 522.2424 Sodium thiamylal.

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§ 522.2483 [Amended]

30. In paragraph (b) of § 522.2483, remove “000010” and in its place add “054628”.

§ 522.2662 [Amended]

31. In paragraph (b)(1) of § 522.2662, remove “000010” and in its place add “054628”.

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

32. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.1580b [Amended]

33. In paragraph (b)(1) of § 524.1580b, remove “000010, 000069, 050749, 054925, 058005, and 061623” and in its place add “000069, 050749, 054628, 054925, 058005, and 061623”.

§ 524.1580c [Amended]

34. In paragraph (b) of § 524.1580c, remove “000010 and 000069” and in its place add “000069 and 054628”.

PART 526--INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

35. The authority citation for 21 CFR part 526 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 526.1696b [Amended]

36. In paragraph (b) of § 526.1696b, remove “000010” and in its place add “054628”.

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

37. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 529.1044a [Amended]

38. In paragraph (b) of § 529.1044a, remove “000010, 000061, 000856, 000859 057561, 058005, and 061623” and in its place add “000061, 000856, 000859, 054628, 057561, 058005, and 061623”.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

39. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.205 [Amended]

40. In paragraph (a) of § 558.205, remove “000010” and in its place add “054628”.

Dated: March 26, 2013.

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